

REMARKS

This is in response to the Office Action mailed on August 23, 2004, and the references cited therewith.

Claims 10 and 17 are amended; claims 1-22 are pending in this application.

Double Patenting Rejection

Claim 1 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of Lange et al. (U.S. Patent No. 6,712,789). Claim 1 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of Lange et al. (U.S. Patent No. 6,712,789). Applicant will submit a terminal disclaimer once the claims are indicated to be in condition for allowance.

Claim 2 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 15 of Kraus (U.S. Patent No. 6,641,564). Applicant respectfully traverses the rejection of claim 2. Applicant cannot find in claim 15 of the '564 patent a "movable valve assembly movable from the second position to the first position along the introducing apparatus while the medical instrument is disposed through the sheath passage along at least the sheath proximal end" as recited in claim 1, from which claim 2 depends. Reconsideration and allowance of claim 2 are respectfully requested.

§102 Rejection of the Claims

Claims 1, 9 and 10-13 were rejected under 35 USC § 102(b) as being anticipated by Walker et al. (U.S. Patent No. 5,755,693). Applicant respectfully traverses the rejection.

With respect to rejections under 35 U.S.C. 102(b), every element of the claimed invention must be *identically* shown in a single reference in order to anticipate the claim. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). "The identical invention must be shown in as complete detail as is contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). In addition, in order to anticipate the elements in the single reference "must be arranged as in the claim under review." *Id.*, (quoting *Lindemann Maschinenfabrik v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458, 221 USPQ 481, 485

(Fed. Cir. 1948)). Finally, “the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public.” *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1479, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1989).

Applicant submits that the Walker reference fails to legally anticipate claims 1, 9, and 10 – 13 since the reference fails to identically show all of the elements of the claims, and fails to enable all of the elements. For instance, Applicant cannot find in Walker a “movable valve assembly movable from the second position to the first position along the introducing apparatus while the medical instrument is disposed through the sheath passage” as recited in claim 1, and from which claim 9 depends. Furthermore, Applicant cannot find in Walker a “movable valve assembly moves from a second position to a first position along the movable valve longitudinal axis, . . . in the first position the valve is disposed through the longitudinal axis of the sheath, in the second position the valve is disposed away from the longitudinal axis of the sheath” as recited in claim 10, from which claims 11 – 13 depend.

According to the Office Action, Walker discloses “the movable valve assembly movable from the second position to the first position along the movable valve longitudinal axis,” Page 5, Office Action, however no support is provided in the Office Action where this can be found. Furthermore, the Office Action states West discloses “the movable valve assembly movable from the second position to the first position along the introducing apparatus while the medical instrument is disposed (See Fig. 15) through the sheath passage.” Page 5, Office Action Applicant respectfully traverses. No movement of the device supporting such an assertion can be found illustrated in Figure 15. Furthermore, it is unclear how this could occur with a medical device within the sheath passage. Upon review of the supporting text for Figure 15, Col. 8, Lines 5-11, Applicant cannot find any description, nor enabling description to support such an assertion.

Reconsideration and allowance of the rejected claims are respectively requested.

§103 Rejection of the ClaimsClaims 2-8, 14 - 16

Claim 14 was rejected under 35 USC § 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of Pohndorf et al. (U.S. Patent No. 5,441,504). Claim 15 was rejected under 35 USC § 103(a) as being unpatentable over Walker (as applied to claim 1 above) in view of West (U.S. Patent No. 6,322,541). Claims 2-7 and 16 were rejected under 35 USC § 103(a) as being unpatentable over Walker (as applied to claims 1 and 16 above) in view of Pohndorf et al. (U.S. Patent No. 5,441,504). Claim 8 was rejected under 35 USC § 103(a) as being unpatentable over Walker in view of Pohndorf et al. (as applied to claim 1), and further in view of West et al. (U.S. Patent No. 6,322,541).

Applicant respectfully traverses the rejection and submits that the Office Action fails to establish a *prima facie* case of obviousness, because all of the elements cannot be found in the cited reference. For instance, Applicant cannot find in Walker a “movable valve assembly movable from the second position to the first position along the introducing apparatus while the medical instrument is disposed through the sheath passage” as recited in claim 1, and from which claims 2 – 8 depend. Furthermore, Applicant cannot find in Walker a “movable valve assembly moves from a second position to a first position along the movable valve longitudinal axis, . . . in the first position the valve is disposed through the longitudinal axis of the sheath, in the second position the valve is disposed away from the longitudinal axis of the sheath” as recited in claim 10, from which claims 14 – 16 depend.

Notwithstanding that the references fail to establish all of the elements of the claims, Applicant submits the Office Action fails to establish a *prima facie* of obviousness, because there is no *objective* motivation to combine the references. According to the Office Action “it would be obvious . . . since the use thereof would provide an improved introducer.” Office Action, Pages 7, 8, and 9. Applicant notes that no objective support is provided for such an assertion. Applicant respectfully submits that such an assertion cannot legally support a motivation to combine the references.

As the Federal Circuit has stated: “Virtually all inventions are combinations of old elements. . . . If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding

prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention.” *Yamanouchi Pharmaceutical Co. v. Danbury Pharmacal Inc.*, 56 U.S.P.Q.2d 1641, 1644 (Fed. Cir. 2000), quoting *In re Rouffet*, 149 F.3d 1350, 1357-1358, 47 U.S.P.Q.2d 1453, 1457 (Fed. Cir. 1998).

Instead, motivation to combine the references must be found in the prior art, and not based on Applicant’s disclosure. Furthermore, a showing of a suggestion, teaching, or motivation to combine prior teachings “must be clear and particular . . . Broad conclusory statements regarding the teaching of multiple references, standing along, are not ‘evidence.’” *In re Dembicza*k, 175 F.2d 994, 50 USPQ2d 1614 (Fed. Cir. 1999).

Applicant submits that the statement “would provide an improved introducer” is broad and unsupported, and cannot be found in the cited references. Applicant submits that the Office Action fails to provide a legally sufficient motivation to combine the references. Reconsideration and allowance of claims 2 – 8, 14 - 16 are respectfully requested.

Claims 17 – 22

Claims 17-22 were rejected under 35 USC § 103(a) as being unpatentable over Walker et al. (U.S. Patent No. 5,755,693) in view of West et al. (U.S. Patent No. 6,322,541). Applicant respectfully traverses the rejection and submits that the Office Action fails to establish a *prima facie* case of obviousness, because all of the elements cannot be found in the cited reference. For instance, Applicant cannot find in the cited references “a side port assembly coupled with the sheath with the coupling, and the side port assembly includes one or more features allowing for the side port to be released from the sheath without damage or separation of the sheath or the side port” as recited in claim 17, from which claims 18 – 22 depend.

According to the Office Action, the “patent to West . . . teaches that it is conventional in the art of a vascular introducer, to utilize a side port assembly (19, 20), snap-fitted or thread connected to an introducer sheath (12).” Page 8, Office Action. Applicant respectfully traverses. While West states “the hub 22 and the end cap 24 include a means for compressive connection therebetween, such as a snap-fit connection or a threaded connection.” West, Col. 3, Lines 4 – 7, Applicant cannot find any such teaching for the side port assembly 19, 20.

Notwithstanding that all of the elements are not established by the references, the Office Action fails to establish a *prima facie* case of obviousness since there is no motivation to combine the references as required by 35 USC 103. The assertion that “it would be obvious . . . since the use thereof would provide an improved introducer” fails to provide a legally sufficient motivation to so selectively combine the references, as further discussed above.

Reconsideration and allowance of claims 17 – 22 are respectfully requested.

Miscellaneous

Applicant respectfully reserves the right to traverse the unsupported assertions under MPEP 2144.

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Serial Number: 10/804,596

Filing Date: March 18, 2004

Title: INTRODUCER HAVING A MOVABLE VALVE ASSEMBLY WITH REMOVABLE SIDE PORT

Page 11
Dkt: 905.020US2

Conclusion

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 359-3276 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

MICHAEL LANGE ET AL.

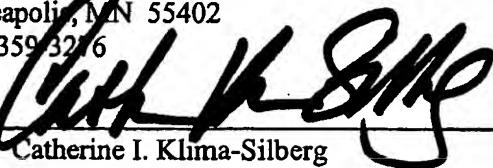
By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938
Minneapolis, MN 55402
(612) 359-3276

Date

Nov. 17, 2004

By


Catherine I. Klima-Silberg
Reg. No. 40,052

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of November, 2004.

CANDIS BUENDING

Name

Candy Buending

Signature